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2005

David R. Saliwanchik, Patent Attorney

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INFORMATION DISCLOSURE **STATEMENT** Patent Application Docket No. GJE-7230 Serial No. 10/531,333

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner

1

not yet assigned

Art Unit

not yet assigned

Applicants

John Gary Montana, Ian Fleming, Reinhold Tacke, Jurgen Daiss

Serial No.

10/531,333 <

Filed

April 14, 2005

Conf. No.

not yet assigned

For

Heterocyclic Silicon Compounds and Their Use in the Treatment of Diseases

or Conditions Associated with GNRH (Gonadotropin-Releasing Hormone)

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

## INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§1.97 AND 1.98

Sir:

The above-referenced patent application was filed in the U.S. Patent Office as a national application under 35 USC §371. Copies of the International Search Report and copies of the references cited therein were made available in the national stage file; however, for the Examiner's convenience, the applicants are enclosing herewith copies of the cited references as well as a copy of the International Search Report.

Attached is a PTO/SB/08 form which lists the references attached.

In accordance with 37 CFR §1.56, the applicants hereby request that the references cited in the International Search Report and listed on the attached form PTO/SB/08 be made of record and considered in the examination of the subject application.

Applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

David R. Saliwanchik

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Attachment: Form PTO/SB/08; copies of cited references

Copy of International Search Report.

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for fo	rm 1449A/PTO			Complete if Known		
		<u> </u>	DE	Application Number	10/531,333	
	ATION DIS			Filing Date	April 14, 2005	
STATEMENT BY APPLICANT				First Named Inventor	John Gary Montana	
(4	use as many she	ets as ne	ecessary)	Art Unit	Not yet assigned	
				Examiner Name	Not yet assigned	
Sheet	1	of	2	Attorney Docket Number	GJE-7230	

	U.S. PATENT DOCUMENTS								
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear				
	U1	US-							
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	U9	US-							

FOREIGN PATENT DOCUMENTS								
Examiner	Cite	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
	No. 1	Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				T⁴		
	F1	WO 03/106446	12-24-2003	Pfizer Inc.	All			
	F2	WO 03/068769	08-21-2003	Pfizer Inc.	All			
	F3	WO 00/20358	04-13-2000	Agouron Pharmaceuticals, Inc.	All			
	F4					Г		
	F5							
	F6							
	F7							

	Examiner	Date
1	Signature	Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kind Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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	RMATION			Filing Date	April 14, 2005		
STAT	EMENT B	Y APPLI	CANI	First Named Inventor	John Gary Montana		
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(us	e as many snee	is as necess	ary)	Examiner Name			
Sheet	2	of	2	Attorney Docket Number	GJE-7230		

	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>				
	R1	ANDERES, K. L. et al. "Biological Characterization of a Novel, Orally Active Small Molecule Gonadotropin-Releasing Hormone (GnRH) Antagonist Using Castrated and Intact Rats" The Journal of Pharmacology and Experimental Therapeutics, May 2003, pp. 688-695, Vol. 305, No. 2.					
	R2	IATSIMIRSKAIA, E. A. et al. "Effect of Testosterone Suppression on the Pharmacokinetics of a Potent GnRH Receptor Antagonist" <i>Pharmaceutical Research</i> , February 2002, pp. 202-208, Vol. 19, No. 2.					
	R3	LUTHIN, D. R. et al. "Characterization of Mono- and Diaminopyrimidine Derivatives as Novel, Nonpeptide Gonadotropin Releasing Hormone (GnRH) Receptor Antagonists" Bioorganic & Medicinal Chemistry Letters, December 16, 2002, pp. 3635-3639, Vol. 12, No. 24.					
	R4	LUTHIN, D. R. et al. "The Discovery of Novel Small Molecule Non-Peptide Gonadotropin Releasing Hormone (GnRH) Receptor Antagonists" <i>Bioorganic &amp; Medicinal Chemistry Letters</i> , December 2, 2002, pp. 3467-3470, Vol. 12, No. 23.					
	R5	TACKE, R. et al. "Sila-Substitution- A Useful Strategy for Drug Design" Endeavour, 1986, pp. 191-197, Vol. 10, No. 4.					
	R6						
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	R13		1				

Examiner	Date	
Signature	 Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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